UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/633,295 | 08/07/2000 | Alfons Nichtl | 100564-00025 | 4590 |

7590 12/13/2002

Arent Fox Kintner Plotkin & Kahn PLLC
1050 Connecticut Avenue N W Suite 600
Washington, DC 20036-5339

| EXAMINER | |
|---|---|
| DO, PENSEE T | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1641 | 17 |

DATE MAILED: 12/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/633,295 | NICHTL, ALFONS | |
| | Examiner | Art Unit | |
| | Pensee T. Do | 1641 | |

*-- The MAILING DATE of this communication appears on the cover she t with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *26 September 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *24-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

### Amendment Entry & Claim Status

The amendment filed on September 26, 2002 has been acknowledged and entered.

Claims 24-39 are pending.

### *Withdrawn Rejection(s)*

Rejection under 35 USC 112, 1st paragraph is withdrawn herein.

Rejection under 35 USC 102(b) by Olsen is withdrawn herein.

### *New Grounds of Rejection(s)*

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 24-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 24, 31 are confusing because of the recitation:

"loading particles with the solution without adversely influencing the function of the conjugates by displacing the biomolecules by the detergent or by interactions of the biomolecules or the colloidal particles with the detergent after loading."

What does the particles (being loaded) have anything to do with displacing the biomolecules by the detergent? At this point, the detergent has been added

already. If any displacement occurs, it would have been taken placed before loading the particles to the solution.

***Maintained Rejection(s)***

***Claim Rejections - 35 U.S.C. § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 24, 30, 31 and 33 are rejected under 35 U.S.C. 102(e) as being anticipated by Liberti et al. (US 5,597,531).

Liberti teaches a coating process comprising coating a wide range of materials (including dextran, proteins, synthetic polypeptides, polymers, detergents, polyethylene glycol and combinations thereof) onto colloidal

magnetically responsive particles to obtain stable microagglomerants. The process comprises the following steps:

(a) forming a liquid mixture of a particulate magnetic starting material and a coating material;

(b) treating the mixture to subdivide the particles of the magnetic starting material;

(c ) permitting the coating material to form a coating on the subdivided particles of the magnetic starting material to form stable, resuspendable coated particles;

(d) recovering the resuspended coated magnetic particles from the liquid mixture. (See col. 4, lines 45-52; claim 1).

***Claim Rejections - 35 U.S.C. § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 25-29, 32 , 34-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liberti et al. (US 5,597,531) further in view of Nichtl et al. (US 5,972,720).

Liberti teaches a coating process comprising coating a wide range of materials (including dextran, proteins, synthetic polypeptides, polymers,

detergents, polyethylene glycol and combinations thereof) onto colloidal magnetically responsive particles to obtain stable microagglomerants. The process comprises the following steps:

(a) forming a liquid mixture of a particulate magnetic starting material and a coating material;

(b) treating the mixture to subdivide the particles of the magnetic starting material;

(c ) permitting the coating material to form a coating on the subdivided particles of the magnetic starting material to form stable, resuspendable coated particles;

(d) recovering the resuspended coated magnetic particles from the liquid mixture. (See col. 4, lines 45-52; claim 1).

Liberti also fails to teach an additional stabilizer such as an inert protein or/and polyethylene glycol after loading the colloidal particles and colloidal particles selected from the group consisting of gold, silver, copper, platinum, palladium and mixture thereof.

Nichtl teaches that after the colloidal particles have been loaded with the respective desired biomolecule, it is necessary to stabilizer the conjugates. This stabilization minimizes an aggregation of the particles and to saturate the remaining free surfaces accessible to adsorption. In the state of the art inert proteins, e.g. bovine serum albumin, detergents, and polymers such as polyethylene glycol, polyvinylpyrrolidone, polyvinyl alcohol, polyvinyl sulfate,

dextran and gelatin are used as stabilizers. Nichtl also teaches a new stabilizer, thiol-substituted polyethylene glycol, which is added to the conjugate of gold particles or metallic particles such as particles of metals, metal oxides, metal hydroxides, metal compounds or particles coated with metals or metal compounds. The metal particles are selected from the group consisting of gold, silver, copper, platinum, palladium, and mixture thereof. (see col. 1, lines 47-61; col. 2, lines 25-28; col. 2, line 53-col. 3, line 7).

It would have been obvious to one of ordinary skills in the art to add the an inert protein selected among those taught in Nichtl to the conjugate formed by the method of Liberti since Liberti and Nichtl both teach improving the long-term stability of the conjugates and lowering the aggregation or agglomeration tendency in solution. (see Nichtl col. 2, lines 25-36).

***Response to Arguments***

Applicant's arguments filed September 26, 2002 have been fully considered but they are not persuasive.

Regarding the 102/103 rejections, applicant submits that Liberti et al. does not teach or suggest the absence of adverse influence on "the function of the conjugates by displacing the biomolecules by the detergent or by interactions of the biomolecules or the colloidal particles with the detergent after loading", as required by the claims.

Liberti inherently teaches this negative limitation since Liberti teaches that the coating of the detergent and biomolecules on the particles is stabilized on the surface of the particles. Although the colloidal particles are coated with detergent, Liberti does not

detect any adverse influence on the function of the conjugates. Furthermore, the biomolecules are not displaced by the detergent because these biomolecules and the detergent can be in a mixture before the particles are loaded for coating.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 703-308-4398. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the

organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-746-5291 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Christopher L. Chin

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641

Pensee T. Do
Patent examiner
December 12, 2002